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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,323	09/01/2000	Michael R. Hayden	50110/004002	5878

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/654,323

Applicant(s)

HAYDEN ET AL.

Examin r

David J. Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51,57-84 and 92-94 is/are pending in the application.
- 4a) Of the above claim(s) 1-49,57-79 and 92-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 50,51 and 80-84 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Application/Control Number: 09/654,323

Page 2

Art Unit: 1652

## **DETAILED ACTION**

### ***Application Status***

- [1]** Claims 1-51, 57-84, and 92-94 are pending in the application.
- [2]** Applicant's amendment to the specification, cancellation of claims 52 and 53 and amendment to claims 50, 51, 80, and 81 in Paper No. 20, filed April 22, 2003, is acknowledged.
- [3]** It is noted that applicant requests cancellation of claims 54-56 in Paper No. 20. These claims have already been canceled in Paper No. 17.
- [4]** Claims 1-49, 57-79, and 92-94 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.
- [5]** Applicant is advised to identify polymorphisms by reference to a nucleic acid or amino acid sequence identified by a specific "SEQ ID NO:" in the claims.

### ***Supplemental Election/Restrictions***

- [6]** This supplemental restriction requirement is at the discretion of the examiner (see MPEP 802 and 37 CFR 1.142) and is deemed appropriate and necessary in view of the plurality of patentably distinct inventions encompassed by claims 50, 51, and 80-84.
- [7]** Because claim 50 recites "at least one polymorphism", restriction to one OR a specific combination of the following inventions is required under 35 USC 121:
  - I.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting a Q597R polymorphism in an ABC1 protein, classified in class 435, subclass 6.
  - II.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting a  $\Delta$ L693 polymorphism in an ABC1 protein, classified in class 435, subclass 6.

Art Unit: 1652

- III.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting an R909X polymorphism in an ABC1 protein, classified in class 435, subclass 6.
- IV.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting a T929I polymorphism in an ABC1 protein, classified in class 435, subclass 6.
- V.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting a M1091T polymorphism in an ABC1 protein, classified in class 435, subclass 6.
- VI.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting an IVS24+1 G→C polymorphism in an ABC1 protein, classified in class 435, subclass 6.
- VII.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting a C1477R polymorphism in an ABC1 protein, classified in class 435, subclass 6.
- VIII.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting a  $\Delta(E,D)1893,94$  polymorphism in an ABC1 protein, classified in class 435, subclass 6.
- IX.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting a R2144X polymorphism in an ABC1 protein, classified in class 435, subclass 6.
- X.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting a  $\Delta C6825 \rightarrow 2145X$  polymorphism in an ABC1 protein, classified in class 435, subclass 6.

Art Unit: 1652

**XI.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting a P2150L polymorphism in an ABC1 protein, classified in class 435, subclass 6.

**XII.** Claim(s) 50, 51, and 80-84, drawn to a method for determining a propensity for developing a disease or condition by detecting a CTC6952-4TT→2203X polymorphism in an ABC1 protein, classified in class 435, subclass 6.

**[8]** The inventions are distinct, each from the other because:

**[9]** Each of the ABC1 polymorphic proteins of Groups I-XII is structurally distinct and thus the methods of Groups I-XII are independent as they utilize different products.

**[10]** MPEP § 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP § 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02". Because the inventions of Groups 1-XII are distinct for the reasons given above and each of the inventions requires a separate patent and non-patent literature and sequence search, restriction for examination purposes is proper.

**[11]** It is noted that claims 50, 51, and 80-84 will be examined only to the extent the claims read on the elected one OR specific combination of polymorphisms.


**[12]** Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**[13]** Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.  
Patent Examiner  
Art Unit 1652

 06/19/03